

63. (New) The method of claim 17, wherein the polymerizable material (prepolymer) is an acrylate.--

### **Remarks**

Claims 17-24 and 50-61 are pending in the application. Claims 19-22 have been withdrawn from consideration. Claims 17, 18, 23, 24, 50, and 53-61 stand rejected, and claims 51 and 52 have been objected to. Claim 17, 51, and 58 have been amended. New claims 62 and 63 have been added. Support for claims 62 and 63 can be found on page 8 at lines 10-12. No new matter is added to the Specification by these changes. Applicant respectfully requests reexamination and reconsideration of the case, as amended. Each of the rejections levied in the Office Action is addressed individually below.

**I. Rejection under 35. U.S.C. § 112, first paragraph, for lack of enablement.** Claims 17, 18, 23, 24, 50, and 53-61 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner states that while the specification is enabling for polymerizable material with unsaturated functional groups, it does not reasonably provide enablement for any polymerizable material. Independent claim 17 has been amended to include polymerizable material with unsaturated functional groups as suggested by the Examiner. Applicant submits that the present amendment obviates this rejection and requests that the rejection be removed.

**II. Rejection under 35 U.S.C. § 112, second paragraph, for indefiniteness.** Claim 58 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has objected to the phrase “limited toxicity” as being vague and subjective. Applicant has amended claim 58 to recite “no toxicity” thereby obviating the present rejection.

In view of the forgoing arguments, Applicant respectfully submits that the present case is now in condition for allowance. A Notice to that effect is requested.

Please charge any fees that may be required for the processing of this Response, or credit any overpayments, to our Deposit Account No. 03-1721.

Respectfully submitted,



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**Appendix A**  
**Clean Copy of Claims as Amended**

17. (Twice Amended) A method of drug delivery, the method comprising steps of:  
introducing into an animal's body (i) a polymerizable material (prepolymer), wherein the polymerizable material includes unsaturated functional groups,  
(ii) a thermal polymerization initiator selected from the group consisting of 2,2'-azobis-[N,N'-dimethyleneisobutyramidine] dihydrochloride and derivatives of 2,2'-azobis-[N,N'-dimethyleneisobutyramidine] dihydrochloride, and  
(iii) a diagnostic, therapeutic, or prophylactic agent; and  
applying thermal energy transdermally for a sufficient amount of time to polymerize or crosslink the said prepolymer, or allowing the pre-polymer to polymerize or crosslink using only the animal's own body heat as a thermal energy source.

18. The method of claim 17 wherein the step of providing an agent comprises providing a bioactive agent.

19. The method of claim 17 wherein the step of providing an agent comprises providing a protein.

20. The method of claim 17 wherein the step of providing an agent comprises providing a peptide.

21. The method of claim 17 wherein the step of providing an agent comprises providing a vaccine.

22. The method of claim 17 wherein the step of providing an agent comprises providing a polynucleotide.

23. The method of claim 17 wherein the step of providing an agent comprises providing an organic compound.

24. The method of claim 17 wherein the step of providing an agent comprises providing an agent within a microsphere.

50. The method of claim 17 wherein the polymerizable material is biodegradable before and after polymerization.

51. (Amended) The method of claim 17 wherein the polymerizable material has unsaturated functional groups selected from the group consisting of alkenes, alkynes, carbonyls, imines, nitriles, cyano, cyanates, isocyanates, iso-cyano, amides, esters, ketones, aldehydes, ureas, carbonates, carbamates, carboxylic acids, phenyl, aryl, and heteroaryl.

52. The method of claim 17 wherein the polymerizable material has functional groups selected from the group consisting of acroyl, methacroyl, allyl, and vinyl.

53. The method of claim 17 wherein the polymerizable material is a hydrogel.

54. The method of claim 17 wherein the polymerizable material and thermal initiator are covalently linked together.

55. The method of claim 17 wherein the step of introducing comprises introducing the material and initiator under the skin, into a muscle, into a body cavity, into a potential space, or into an organ.

56. The method of claim 17 wherein the thermal polymerization initiator initiates polymerization between 37°C and 45°C.

57. The method of claim 17 wherein the thermal polymerization initiator is water soluble.

58. (Amended) The method of claim 17 wherein the thermal polymerization initiator has no toxicity in animals.

59. The method of claim 17 wherein the step of introducing comprises injecting said prepolymer and said initiator using a syringe.

60. The method of claim 17 wherein the step of introducing comprises placing said prepolymer and said initiator during a surgical procedure.

61. The method of claim 17 wherein the step of applying thermal energy comprises applying thermal energy from a heat source selected from the group consisting of a heating pad, a water bath, a hot water bottle, a heat lamp, and a light.

62. (New) The method of claim 17, wherein the polymerizable material (prepolymer) is selected from the group consisting of acrylates, diacrylates, oligoacrylates, methacrylates, dimethacrylates, and oligomethacrylates.

63. (New) The method of claim 17, wherein the polymerizable material (prepolymer) is an acrylate.